REMARKS

THE AMENDMENTS AND REASONS FOR AMENDMENTS

Applicant amends claims 1 and 8-44. Claims 44 and 45 have been withdrawn from consideration because of a Restriction Requirement. The amended claims add no new subject matter and are fully supported by the application, including the specification, figures, and claims as originally filed.

The amendments are made to correct the sequential numbering of the claims and also to clarify the claimed invention in order to expedite the allowance of the present application. Applicant reserves the right to file applications claiming the benefit of priority to the present application claiming the subject matter of the present and other applications.

CLAIM OBJECTIONS

The Examiner has objected to numbering of the claims for not being in accordance with 37 C.F.R. § 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. The Examiner states that the application contains two claims numbered 7, two claims numbered 38, and two claims numbered 39.

The Examiner has renumbered the claims to correct the misnumbered claims and the discrepancies for the purpose of this Office Action, and now, Applicant has amended claims 8 through 44 in order to correct all the misnumbered claims and all references and discrepancies thereof by amendment. Thus Applicant respectfully requests that this objection be withdrawn.

THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner has rejected claims 1-22 and 41-44 under 35 U.S.C. § 112, second paragraph, as allegedly lacking antecedent basis for the phrase "said mixture." The Examiner alleges that the phrase "said mixture" in step (d) of claim 1 lacks antecedent basis.

Applicant respectfully disagrees with the Examiner with respect to this rejection, however, in order to expedite allowance of the claims, Applicant has amended has amended claim 1, namely

the step (b) of claim 1 to provide for "mixing said binding construct with said sample in a mixture to form construct-compound complexes" which is deemed to provide adequate antecedent basis for step (d). Applicant has also amended claims 41-44 to depend from independent claim 23, instead of dependent claim 21. The amendments have rendered this rejection moot. Thus, claims 1-22 and 41-44 are definite under 35 U.S.C. § 112, second paragraph. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

THE PRIOR ART FAILS TO ANTICIPATE THE CLAIMED INVENTION UNDER 35 U.S.C. § 102

The Examiner rejected claims 1-15, 19, 20, 23-37, 41, and 42 under 35 U.S.C. § 102(e) as allegedly being anticipated by Blackburn et al. (US Pat. No. 6,686,150). The Examiner alleges that Blackburn et al. teach a method for detecting a compound of interest in a sample which anticipates the rejected claims.

Applicant respectfully disagrees with the Examiner's characterization of the teachings of Blackburn et al. as alleged in the Office Action at issue. Applicant notes that the claimed invention provides for a binding construct comprising a non-nucleic acid recognition portion which recognizes and binds said non-nucleic acid compound of interest without capture on a solid support, and a nucleic acid portion." This in contrast to the teachings of Blackburn et al., which describes a detection method using nucleic acid probes that hybridize with DNA targets of interest. This probe of Blackburn et al. is not the same as the binding construct of the claimed invention. In the simplest contrast, for Blackburn, amplification is required as part of the recognition process and before any separation of unbound "binding complexes". Detection of amplified product can, but does not require, the separation of unbound "binding construct." The removal of these probes (by a separation sequence) requires nucleic acid and is used after amplification and only to decrease background. In some preferred methods of the claimed invention, the separation is required prior to amplification and it is an integral part of the detection of a target that is a non-nucleic acid compound of interest. The certain embodiments of the claimed invention use primers only after adding accessible binding targets, whereas, Blackburn uses them before. According to the teachings of Blackburn et al., amplification is required as part

of the target recognition, therefore, the target is amplified. The methods of the claimed invention do not amplify the target, the preferred methods of the claimed invention use reporter amplification not target amplification.

The disclosure of Blackburn et al. teaches the use of antibodies (whole, Fab or recombinant single binding molecules) and/or antigens to bind out uncleaved probes that are part of an amplification process. The preferred methods of the clime invention only uses accessible binding surfaces to remove the initial binding construct before amplification. All of the Blackburn et al.'s removal processes are for detection after amplification.

Furthermore, the methods of the present invention teach the detection of a non-nucleic acid compound of interest in the solution phase, without capture on a solid support, and preferably, amplification in that phase after the removal of other amplifiable molecules. In every respect of the teachings of the in the detection method of Blackburn et al., there is a need for a solid support and capture of the compound of interest on that solid support. One of the novelties of the claimed invention is that a solid support is not used to capture the non-nucleic compound of interest in solution.

To expedite allowance of claims, Applicant has amended claims 1 and 8-44 to more clearly claim the invention rendering this rejection moot. Thus, Blackburn et al. does not anticipate the claims. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

APPLICANT'S CLAIMED INVENTION IS NOT OBVIOUS UNDER 35 U.S.C. § 103(A) IN VIEW OF THE REFERENCES CITED BY THE EXAMINER

The Examiner rejected claims 1-44 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baez et al. (US Pat. No. 6,511,809) in view of Blackburn et al. (US Pat. No. 6,686,150). The Examiner alleges that Baez et al. teach a method for detecting a compound of interest in a sample similar to the element of the claimed invention, except for the step of (d) introducing said one or more surfaces to said mixture of said binding construct and said sample in order for said one or more surfaces to form construct-surface complexes with any unbound binding constructs, and the step of (e) separating said construct-surface complexes from said mixture leaving behind said

construct-compound complexes. The Examiner further alleges that the Blackburn et al.'s teachings makes up for the shortcomings of Baez et al. The Examiner, therefore, alleges that the claimed invention would have been obvious to one of ordinary skill in view of the cited references.

Applicant respectfully disagrees with the Examiner's characterization of the teachings of Baez et al. and Blackburn et al. as alleged in the Office Action at issue. The Blackburn et al. reference has been addressed above, and neither Blackburn et al. or Baez et al., separately or together, teach or make obvious each and every elements of the claimed invention.

Baez et al. describe a method for the detection of a specific analyte, wherein the method involves the formation of an analyte-dependent reporter complex that composes (i) an Analyte and (ii) at least two reporter conjugates bound to the Analyte." The diagrams provided by Baez et al. depict this complex where two DNA-labeled antibodies are utilized to sandwich capture the Analyte, which come together to form a unique DNA structure once they are bound to captured analyte that is subsequently cleaved and amplified. In addition, Baez et al. describes a method where a sandwich assay of the antigen is required between the capture antibody and at least two antibodies that form a bridge that creates a unique DNA template that is then amplified to indicate capture of the molecule of interest. The present invention, in contrast, is far less complex and includes a simple binding step and a removal step for unbound binding construct prior to amplification.

The disclosure of Baez et al. also teach the use of solid phase capture of the compound of interest, whereas the methods of the claimed invention do not require the use of solid support capture of the non-nucleic acid compound of interest. The disclosure of Baez et al, provides for a binding construct that is at first the solid phase capture of the analyte by a non DNA-labeled antibody. A DNA-labeled construct is, therefore, not the first molecule in the Baez et al. assay to bind the analyte of interest. The DNA-conjugated antibodies bind to the analyte only after it is captured by this first antibody, which is bound to a solid support, thus exemplifying solid phase capture. The claimed invention uses solution phase capture, wherein DNA conjugated structures bind the analyte of interest in solution, in which the DNA-conjugated binding constructs are the

first molecule to bind the analyte of interest, unlike the teaching of Baez et al. where the DNA conjugated structures the second molecule to bind the analyte of interest. Thus, Baez et al. does not make up for the shortcomings of Blackburn et al.

In order to expedite allowance of claims, Applicant has amended claims 1 and 8-44 to more clearly claim the invention rendering this rejection moot. Thus, Baez et al. and Blackburn et al., either separately or together, do not make the claimed invention obvious. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Applicant respectfully submit that the claims are ready for examination and in condition for allowance.

Respectfully submitted,

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Thomas D. Foster
Reg. No. 44,686

12760 High Bluff Drive, Ste. 300
San Diego, CA 92122

Telephone: 858-922-2170
Facsimile: 858-359-6008